Cura Medical Technologies LLC
23 Rancho Circle
Lake Forest, CA 92630
949-716-2447
www.curamedtech.com

MAR 0 4 2013

December 14, 2012

PTS-250, Proton Radiation Beam Therapy System
Premarket Notification (510(k)) Summary,
as required by 21 CFR 807.92(c)

Introduction

This document provides a summary of the safety and effectiveness information contained in the Cura Collimator Premarket Notification (510(k)). This Premarket Notification (510(k)) Summary contains no confidential or trade secret information and is intended for full public disclosure and distribution. For addition information, please contact the Establishment's contact listed below, Thomas H. Faris.

Premarket Notification Information

Previous Notificaton Information:

Previous Submission #:	None, Initial Submission
Previous FDA Clearance Date	None
Product Name	Cura Collimator

Submitter's Information :

Cura Medical Technologies
23 Rancho Circle
Lake Forest, CA 92630

Contact Person:

Thomas Faris
Consultant for Quality and Regualtory Affairs
C/O Mevion Medical Systems, Inc.
300 Foster Street
Littleton, MA 01460
Phone: 978 540 1713
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Email: TFaris@mevion.com

Trade Name: Cura Collimator

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Classification Information:

Classification Name	Customer Beam Block
.Proudct Code	IXI
CFR Reference	21 CFR892.5710
Product Classification	Class II
Review Panel	Office of In Vitro Diagnostic Device Evaluation and Safety

Predicate Device:

.Decimal Aperture
K071077

Intended Use/Indications for use

The Cura Collimator is a solid, machine-shaped brass aperture intended to shape an external radiation beam to block radiation from hitting critical structures and healthy tissue while guiding the radiation to the targeted area. The Cura Collimator may be used as an accessory whenever external beam radiation therapy is indicated for the treatment of patients with localized tumors or other conditions susceptible to treatment by radiation.

Summary Device Description

Cura Collimators are custom beam blocks with machined cutout to allow beam passage per prescription and sized to snugly fit the applicator or nozzle and block all remaining beam in the radiation therapy fraction delivery. The Collimator is made of high lead content brass with notch orientation to match radiation machine manufacturer use specifications. No software is included in this device.

Summary of Technological Characteristics

Cura Collimators, sometimes also called *apertures*, are made of brass, custom cut to hospital users' specifications, and used for external beam radiation therapy treatments. The brass aperture cutouts are designed according to the Treatment Plan parameters designated by hospital personnel and then transmitted to Cura machining centers for custom manufacture and delivery back to the hospital.

The device features of Cura Collimators are similar to the predicate device, Dot Decimal's Apertures. They both are made of brass, custom cut to hospital users' specifications, and used for external beam radiation therapy treatments. They both are used to block radiation and guide it to affected areas. The target population is identical and the use parameters are also very similar.

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Summary of Non-Clinical Testing

Cura Collimators were tested for:

1. Material performance
2. Machine tool instructions adherence to Treatment Plan direction
3. DICOM Network Transmission system integrity

Treatment plans were created at Washington University, in St. Louis, Missouri. The treatment plans were transmitted to Cura via Cura's DICOM Network Transmission application. Cura manufactured the Cura Collmators, based upon the communicated treatment plan. Cura distributed the test Cura Collimators to Washington University, who physically compared the Cura Collimators to the actual treatment plan and conducted beam tests with the Cura Collimators. Cura Collimators were also sent to Mevion Medical Systems, Inc. for physical inspection and beam test. For beam test, the Cura Collimators were placed in beam and the delivered field was captured on digital film. Both Mevion and Washington confirmed the accuracy of the delivered beam line field versus the treatment plan.

All tests PASSED, with no contingencies or other considerations.

Conclusion

In conclusion, the non-clinical test demonstrates that Cura Collimators function as intented, and are Safe and Effective to accomplish their intended use.

Summary of Technological Characteristics Substantial Equivalence Analysis

The Cura Collimator is substantially equivalent to .decimal's .decimal Aperture. Brass apertures have been used for beam shaping in radiation therapy for many decades. The Brass apertures effectively shape radiotherapy treatment beams – proton, electron, and photon beams – to precisely deliver radition to intended treatment targets. Cura Collimator is equivalent in intended use, materials used, creation and use processes, and performance. The Cura Collimator poses no new, novel, or different safety or efficacy risks or efficacies. As such, the Cura Collimator is Substantially Equivalent to the .decimal Aperture.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

March 4, 2013

Mr. Thomas H. Faris
Regulatory Counsel
Cura Medical Technologies, LLC
23 Rancho Circle
LAKE FOREST CA 92630

Re: K123893
Trade/Device Name: Cura Collimator
Regulation Number: 21 CFR 892.5710
Regulation Name: Radiation therapy beam-shaping block
Regulatory Class: II
Product Code: IXI
Dated: October 27, 2012
Received: December 18, 2012

Dear Mr. Faris:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Janine M. Morris
Director, Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K123893

Device Name: **Cura Collimator**

Indications for Use:

The Cura Collimator is a solid, machine-shaped brass aperture intended to shape an external radiation beam to block radiation from hitting critical structures and healthy tissue while guiding the radiation to the targeted area. The Cura Collimator may be used as an accessory whenever external beam radiation therapy is indicated for the treatment of patients with localized tumors or other conditions susceptible to treatment by radiation.

Prescription Use __X__ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety

Michael O'Hara

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) 123893